

**Response Under 37 C.F.R. § 1.116
Expedited Procedure
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REMARKS

A. Background

Claims 13-27 were pending in the application at the time of the Office Action. Claims 13-27 were rejected as being obvious over cited art. By this response, Applicant has not amended, canceled, or added any claims. As such, claims 13-27 are again presented for the Examiner's consideration in light of the following remarks.

B. Rejection on the Merits

The Office Action rejected claims 13-27 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Number 4,952,370 to Cummings et al. ("Cummings") in view of U.S. Patent Number 5,173,258 to Childers ("Childers '258") and U.S. Patent Number 5,906,794 to Childers ("Childers '794"). The Office Action asserts that Cummings teaches all the elements of the rejected claims, except that "the Cummings system is not continuously recirculating," and points to Childers '258 and Childers '794 to cure this deficiency of Cummings. Applicant respectfully traverses this rejection.

Applicant respectfully notes at the outset that in order to establish a *prima facie* case of obviousness, it is the burden of the Examiner to demonstrate that three criteria are met: first, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; second, there must be a reasonable expectation of success; and third, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *MPEP* § 2143.

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As detailed in the previous response, Cummings is directed towards a method of sterilizing a sealed enclosure containing surfaces at two disparate temperatures while maintaining the disparate temperatures of the surfaces. See Cummings Abstract. That is, Cummings specifically states that it

is an object of the present invention to provide a process for sterilizing surface within equipment, such as cold centrifuges or refrigerators, having very cold portions without significantly elevating the temperature of the cold portion of the surfaces. It is a further object of the present invention, to provide such a process where two or more surface portions in the same chamber, each having widely differing temperature ranges, can be simultaneously sterilized without significantly altering the temperature of any surface portion.

Col. 2, lines 29-38.

The method of Cummings consists of injecting vapor phase hydrogen peroxide and water into the enclosure through inlet ports (22 and 24) to form a condensate on the surface with the lower temperature. A vacuum pump (40) is then used to evaporate the water within the enclosure and remove it. Abstract and col. 3, lines 51-53. The removed water vapor is processed to remove any hydrogen peroxide and is then dispensed to the atmosphere. The vacuum pump (40) is used to maintain a pressure within the enclosure "above the vapor pressure of hydrogen peroxide and below the vapor pressure of water at the relevant temperature." Col. 3, lines 61-65. By maintaining the pressure in the enclosure between the two vapor pressures, the water evaporates out of the condensate while the hydrogen peroxide does not, resulting in a higher concentration of hydrogen peroxide in the condensate that remains on the cold surface. Col. 3, lines 65-68. Another purpose of the vacuum (40) is to "remove... much of the water vapor to avoid a build up of water vapor in the chamber." Col. 4, lines 17-19.

Additional vapor phase hydrogen peroxide is periodically injected into the enclosure through inlet ports (22 and 24) to replace hydrogen peroxide condensate that degrades into its components

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(water and oxygen) over time and the vacuum pump (40) continues to remove the water vapor as it evaporates. Col. 4, lines 127-19. This process of periodically injecting hydrogen peroxide while withdrawing water vapor under a vacuum continues until the surfaces within the enclosure are sterile. The hydrogen peroxide condensate is then removed from the system by using the vacuum pump (40) to further reduce the pressure in the enclosure so as to cause the hydrogen peroxide condensate to evaporate. Col. 6, line 63 – col. 7, line 2. Once the hydrogen peroxide is removed from the sealed enclosure, the hydrogen peroxide is processed and then discharged to the environment.

The Office Action asserts that Cummings teaches “[t]he concentration, temperature and pressure parameters within the enclosure are monitored and injection of the steam/hydrogen peroxide is actuated in response thereto.” Assuming, *arguendo*, that this is true, Cummings still does not teach

the gas temperature in or exiting the enclosure or entering the preparation region, decontaminant gas concentration in or exiting the enclosure or entering the preparation region and condensation of the decontaminant gas in the enclosure are monitored and the dispensing of the mixture of decontaminant gas and water vapour into the gas in the preparation region is controlled in response to the levels determined by said monitoring,

as recited in claim 13, or

means (17, 18) are provided for monitoring the condensation of the decontaminant gas in or exiting the enclosure or entering the preparation region and said means (19) for controlling the dispensing of the mixture of decontaminant gas and water vapour into the gas in the preparation region are controlled in response to the levels determined by said monitoring to provide a predetermined level of condensation of the mixture of decontaminant gas and water vapour in the enclosure,

as recited in claim 20. Specifically, while Cummings may arguably measure temperature and concentration parameters, as asserted by the Office Action, Cummings does not disclose measuring

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condensation or means for such measuring. Indeed, the Office Action never asserts that Cummings measures condensation or has corresponding means. Instead, according to the Office Action, Cummings measures "concentration, temperature and pressure parameters." Emphasis added. While these parameters may give some indication as to the possibility of condensation, they do not measure condensation. Thus, Cummings does not monitor condensation or have means for monitoring as required by claims 13 and 20.

In one embodiment of the present invention, it has been established that faster and more reliable surface decontamination may be achieved if micro condensation is encouraged and controlled. Micro condensation is established and controlled in part by the ability to directly measure the condensation. See page 3, lines 30-35 and page 7, lines 21-27 of the present application as originally filed. Again, however, Cummings does not disclose or suggest monitoring condensation or means for monitoring condensation.

As described above, the Office Action points to Childers '258 and Childers '794 to cure the deficiency of Cummings of not continuously recirculating the gas. Even if the alleged gas recirculation means of Childers '258 and Childers '794 were combined with the Cummings device in the manner asserted by the Office Action, however, the combination would still not cure the deficiencies of Cummings, described above. Specifically, applicant submits that neither Childers '258 nor Childers '794 disclose a method of sterilizing a sealed enclosure in which "the ... condensation of the decontaminant gas in the enclosure [is] monitored," as recited in claim 13, nor "means ... for monitoring the condensation of the decontaminant gas," as recited in claim 20.

As such, Applicant submits that even assuming, *arguendo*, that the Cummings device was modified

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by Childers '258 and/or Childers '794 in the manner asserted by the Office Action, the combination would still not produce the invention as recited in claims 13 or 20.

Furthermore, Applicant submits that there is no motivation for modifying Cummings with Childers '258 or Childers '794 as proposed by the Office Action. Specifically, there is no motivation to modify Cummings to recirculate any gas that is evacuated from the enclosure of Cummings back into the enclosure. As discussed above, during the sterilization process, the vacuum pump (40) is used to regulate the pressure within the enclosure so that water vapor can be removed under the vacuum while the hydrogen peroxide remains in the enclosure. Cummings teaches that the water vapor is removed "to avoid a build up of water vapor in the chamber." Col. 4, lines 18-19. Accordingly, because the gas that is drawn out of the enclosure during the sterilization process is primarily water vapor, there is no motivation to recirculate this gas back into the enclosure. Also, although the hydrogen peroxide is removed from the enclosure after the sterilization process, there is no motivation to pass this hydrogen peroxide back into the enclosure because the enclosure is already sterile.

The Childers '258 or Childers '794 patents do disclose recirculating a sterilization gas through a sealable enclosure and also partially drying the gas to remove a portion of the water vapor therein before passing the gas back through the enclosure. However, the Childers patents recirculate the sterilization gas, in part, because it has a relatively high concentration of hydrogen peroxide. That is, as previously discussed, the gas removed from the enclosure of Cummings has minimum hydrogen peroxide because the pressure is regulated within the enclosure so as to prevent vaporization of the hydrogen peroxide while necessitating vaporization of the water. In contrast, no such pressure regulation is made in the Childers patents because the Childers patents are not

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addressing the problems of enclosures with temperature variations. As a result, the gas removed from the enclosures of the Childers patents has a much higher concentration of hydrogen peroxide.

Accordingly, because there is minimal hydrogen peroxide in the gas exiting the enclosure of the Cummings patent, applicant submits that there is no motivation to one skilled in the art to modify the Cummings reference to include an expensive dryer and all of the other related equipment necessary to facilitate recirculation of the gas when there is no need or benefit for recirculating the gas. Thus, applicant submits that there is no motivation to combine the teachings of the Cummings patents with the Childers '258 patent or the Childers '794 patent in the manner suggested by the Office Action.

In view of the forgoing, applicant submits that because the alleged combination does not teach or suggest all the claim limitations of claims 13 and 20, and because there is no suggestion or motivation to modify Cummings with Childers '258 or Childers '794 in the manner suggested by the Office Action, the Office Action has failed to establish a *prima facie* case of obviousness regarding claims 13 and 20. Accordingly, Applicant respectfully requests that the obviousness rejection with respect to claims 13 and 20 be withdrawn.

Claims 14-19 and 21-27 each depend from claim 13 or 20, and thus incorporate the limitations thereof. As such, applicant submits that claims 14-19 and 21-27 are distinguished over the cited art for at least the same reasons as discussed above with regard to claims 13 and 20. Accordingly, Applicant respectfully requests that the obviousness rejection with respect to claims 14-19 and 21-27 also be withdrawn.

Applicant submits that many if not all of the dependent claims may also be independently distinguishable over the proposed combination. For example, claims 26 and 27 recite "heating the

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gas" (in claim 26), and "means for heating the gas" (in claim 27) "in said preparation region prior to circulation through the enclosure." Cummings does not disclose any heating of or means for heating water vapor or hydrogen peroxide vapor before injection into the enclosure. In fact, Cummings actually teaches against such heating. Specifically, if the mixture was heated before injection into the enclosure, it would necessarily impart at least some of the heat to the enclosure. Yet one of the stated objectives of Cummings is to maintain the cool temperature of the enclosure during sterilization. See col. 2, lines 28-38. To achieve this objective, the vacuum is used so that the hydrogen peroxide and water can be vaporized without applying heat. Thus, Cummings does not disclose heating of the gas or means for heating the gas since such methods and structures are in direct contrast to the intended function and operation of the system of Cummings. As such, applicant also submits that claims 26 and 27 are independently allowable over the cited art.

No other objections or rejections are set forth in the Office Action.

D. Conclusion

In view of the foregoing, applicant respectfully requests the Examiner's reconsideration and allowance of claims 13-27 as presented herein.

In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

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Dated this 19 day of April 2006.

Respectfully submitted,



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